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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,815	04/13/2001	Barnett S. Pitzele	PHAR 7978/3312US	8682

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EXAMINER

ZUCKER, PAUL A

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/834,815

Applicant(s)

PITZELE ET AL

Examiner

Paul A. Zucker

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2002 has been entered.

***Current Status***

2. This action is responsive to Applicants' request for Reconsideration and Terminal Disclaimer of 23 December 2002 in Papers No 10 and 11.
3. Claims 1-28 remain outstanding.
4. The providsional Double Patenting rejection set forth in paragraph 5 of the previous Office Action in Paper No 8 is withdrawn in view of Applicants' execution of a Terminal Disclaimer over application 09/952,888.
5. The rejection under 35 USC § 103 set forth in paragraph 6 of the previous Office Action in Paper No 8 is withdrawn is withdrawn in response to Applicants' remarks.

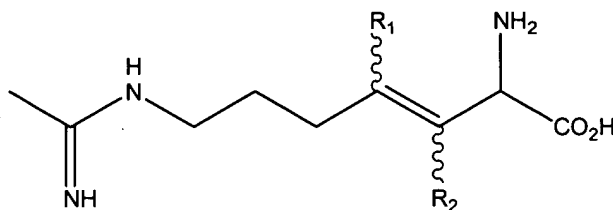
***New Rejection***

***Claim Rejections - 35 USC § 103***

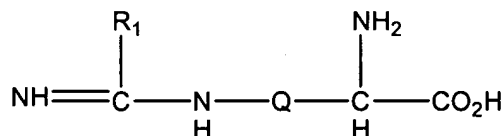
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beams et al (WO 93/13055-A1 07-1993).

The instantly claimed invention is directed toward the compounds (geometric and stereoisomers) and compositions of Formulas (I) and (II), where  $R_1$  and  $R_2$  may be H or methyl, or their pharmaceutically acceptable salts :



Beams teaches (Page 5, line 26-page 7, line 35) a genus of nitric oxide synthase inhibitors of general formula (I):



Where  $R^1$  may be a C<sub>1-6</sub> straight chain or branched alkyl and Q may be an alkylene, alkenylene or alkynylene group having 3-6 carbons. Beams further teaches (Page 5, line 37-page 6, line 1) optional substitution of Q by one or more C<sub>1-3</sub> alkyl groups. A preferred embodiment of the compounds is further taught (Page 6 lines 30-36) where  $Q = -(CH_2)_vCH=CH(CH_2)_w-$  where  $v = 0-3$ ;  $w = 0$  to 3; and  $v + w = 2-4$ . The instantly claimed compounds correspond to  $v = 3$ ,  $w = 0$  and thus fall within the narrow subgenus suggested by Beams (in fact, one of ordinary skill in the art could

immediately envisage all alkylene groups in this subgenus). Beams further teaches (Page 7, lines 1-3) a preferred value for  $R^1$  of methyl. Beams further teaches (Page 3, lines 23-34) that the genus encompasses all stereoisomeric forms (both E,Z and R,S).

Beams' provides further guidance for selection of the alkylene subgenus in the exemplification (Page 13, lines 24-31, Example 3 and page 15, lines 1-10, Example 8) of E and Z ( $\mp$ )-2-Amino-6-(1-iminoethylamino)-hex-4-enoic acid.

Beams further teaches (Page 8, line 14 – page 11, line 4) pharmaceutical compositions of the compounds as well. Beams teaches (Page 16, lines 15 – 25) the instantly desired selective inhibition of the inducible form of nitric oxide synthase using the compounds of his invention.

One of ordinary skill in the art would have had the expectation of similar properties for the instant compounds and that of Beams and the instant compounds are therefore obvious over those of Beams. This is especially true since Beams provides clear guidance for the selection of the identity of the variables  $R_1$  and Q that produce the instantly claimed compounds.

Thus the instantly claimed compounds and pharmaceutical compositions containing them would have been obvious to one of ordinary skill in the art. The motivation for the instantly claimed invention would have been to develop other compounds in the genus taught by Beams and apply them, in the compositions taught by Beams, to the

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methods taught by Beams. There would have been a reasonable expectation for success since Beams' genus completely embraces the instant compounds which, Beams teaches, have the instantly desired activity as nitric oxide synthase inhibitors.

**Conclusion**

7. Claims 1-28 are pending. Claims 1-28 are rejected.

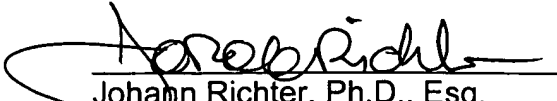
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Paul A. Zucker  
Patent Examiner  
Technology Center 1600

March 20, 2003

  
Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
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